

### REMARKS-General

The amended independent claim 1 incorporates all structural limitations of the original claim 1 and includes further limitations previously brought forth in the disclosure. No new matter has been included. All claims 1-6 and 9-25 are submitted to be of sufficient clarity and detail to enable a person of average skill in the art to make and use the instant invention, so as to be pursuant to 35 USC 112.

#### Response to Rejection of Claims 1-6 and 9-25 under 35USC112

The applicant submits that the amended claims 1-6 and 9-25 particularly point out and distinctly claim the subject matter of the instant invention, as pursuant to 35USC112. The applicant respectfully submits that the terms "Panulownia" and "Glubularia" in the instant invention should be Paulownia and Globularia respectively.

#### Response to Rejection of Claims 1-6 and 9-25 under 35USC103

The Examiner rejected claims 1-6 and 9-25 over Li (N) in view of Song et al (U), Jiang et al. (O), Wang et al. (V), Chen et al. (W), Hsu et al. (X), Takahashi (A\*), Grayer-Berkmeijer (U1), Yoshikawa et al. (v1), Somava et al. (W1), Li et al. (O), and Prasad et al. (X1). Pursuant to 35 U.S.C. 103:

"(a) A patent may not be obtained though the invention is **not identically** disclosed or described as set forth in **section 102 of this title**, if the **differences** between the subject matter sought to be patented and the prior art are such that the **subject matter as a whole would have been obvious** at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made."

In view of 35 U.S.C. 103(a), it is apparent that to be qualified as a prior art under 35USC103(a), the prior art must be cited under 35USC102(a)~(g) but the disclosure of the prior art and the invention are not identical and there are one or more differences between the subject matter sought to be patented and the prior art. In addition, such differences between the subject matter sought to be patented **as a whole** and the prior art are obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains.

In other words, the differences between the subject matter sought to be patent as a whole of the instant invention and Li which is qualified as prior art of the instant invention under 35USC102 are obvious in view of Song, Jiang, Wang, Chen, Hsu, Takahashi, Grayer-Berkmeijer, Yoshikawa, Somava, Li et al, and Prasad at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains.

The applicant respectfully submits that in order to determine whether the differences between the subject matters sought to be patent as a whole of the instant invention and the primary prior art, Li, are obvious in view of the supplemental cited arts, Song, Jiang, Wang, Chen, Hsu, Takahashi, Grayer-Berkmeijer, Yoshikawa, Somava, Li et al, and/or Prasad, we have to identify all the differences between the claims of the instant inventions and Li. The applicant respectfully identifies the differences between the claims of the instant invention and Li as follows:

(a) In claim 1, "the composition is used for treating living object with non-insulin dependent diabetes mellitus" is claimed, wherein Li merely teaches a tablet for lowering blood sugar. The applicant respectfully submits that the composition is a treatment for living object with non-insulin dependent diabetes mellitus. A mere recitation of the providing a blood sugar-lowing tablet does not anticipate or suggest any composition for treating living object with non-insulin dependent diabetes mellitus. The application respectfully submits the composition of the instant invention is successfully used for treating living objects, i.e. mice, rabbit, and human being, as illustrated in the Figures.

(b) In claim 1, "the composition comprises a berberine as a first active ingredient and a catalpol as a second active ingredient" is claimed for treating living object with non-insulin dependent diabetes mellitus. Li merely teaches the traditional Chinese medicine is selected from astragalus root, Ginseng, figwort, Chinese yam, medlar, radices rehmanniae, cortex lycii radicis, radices puerarrire, rhizome polygonati, scutellaria, Phellodendron rupr, pieplant, fructus schizandrae, honeysuckle, rhizome anemarrhenae, rhizome attractylodis, radices polygonati, officinalis, truckahoe, lily, radices trichosanthis, etc. However, Li fails to teach any composition comprising berberine and catalpol.

The Examiner alleges that Phellodendron and Rehmannia are known to be sources of the first and second active ingredients. The applicant respectfully submits that Phellodendron and Rehmannia contain different kinds of compositions that Li merely mentions the medicine containing Phellodendron and Rehmannia is not equivalent to the composition of the instant invention containing berberine and catalpol. The only suggestion of Chinese medicine in Li is selected from Phellodendron, Rehmannia, etc.... Besides, Li does not verbally suggest any extraction of berberine and catalpol from Phellodendron and Rehmannia not the step of extracting the berberine and catalpol from Phellodendron and Rehmannia.

(c) Li fails to teach composition further comprises an oleanolic acid as a third active ingredient as claimed in claim 2 in addition to what is claimed in claim 1 as a whole. Accordingly, a mere recitation of providing honeysuckle does not anticipate or suggest any composition containing oleanolic acid. In other words, Li does not disclose what kinds of composition can be extracted from Phellodendron, Rehmannia, and honeysuckle to obtain berberine, catalpol, and oleanolic acid and how the Phellodendron, Rehmannia, and honeysuckle uses for treating living object with non-insulin dependent diabetes mellitus.

(d) Li fails to teach the berberine is extracted from one or more natural herbs selected from the group consisting of Berberis, Chelidonium, Stephniz, Coptis, Phellodendron, and Ziziphus as claimed in claims 3 and 6 in addition to what is claimed in claim 1 as a whole. Li merely suggests the tablet contains Phellodendron without teaching any berberine extracted from Phellodendron. In fact, the instant invention discloses berberine can be extracted from one or more natural herbs of Berberis, Chelidonium, Stephniz, Coptis, Phellodendron, and Ziziphus.

(e) Li fails to teach the catalpol is extracted from one or more natural herbs selected from the group consisting of Rehmannia, Verbascum, Paulownia, Globularia, and Adonis as claimed in claims 4 and 6 in addition to what is claimed in claim 1 as a whole. Li merely suggests the tablet contains Rehmannia without teaching any catalpol extracted from Rehmannia.

(f) Li fails to teach the oleanolic acid is extracted from one or more natural herbs selected from the group consisting of Olea, Swertia, Astrantia, Lonicera, and Beta

as claimed in claim 5 in addition to what is claimed in claim 1 as a whole. Li merely suggests the tablet contains honeysuckle without teaching any oleanolic acid extracted from honeysuckle.

(g) Li fails to teach the composition is prepared into a predetermined form for administration that contains 1 to 300 mg/kg/dl of berberine for treating living object with non-insulin dependent diabetes mellitus as claimed in claims 9 and 10 in addition to what is claimed in claim 1 as a whole. Li is silent regarding any ratio of berberine for administration by living object.

(h) Li fails to teach the composition is prepared into a predetermined form for administration that contains 5 to 1500 mg/kg/dl of berberine for treating living object with non-insulin dependent diabetes mellitus as claimed in claim 11 in addition to what is claimed in claim 1 as a whole. Li is silent regarding any ratio of berberine for administration by living object.

(i) Li is silent regarding the composition is prepared as a draught in water for treating living object as claimed in claims 12 and 21 in addition to what is claimed in claim 1 as a whole. Li merely teaches a tablet has blood sugar lowering effect.

(j) Li is silent regarding the composition is prepared as a syrup for treating living object as claimed in claims 13 and 22 in addition to what is claimed in claim 1 as a whole.

(k) Li is silent regarding the composition is prepared as a cachets for treating living object as claimed in claims 14 and 23 in addition to what is claimed in claim 1 as a whole.

(l) Li is silent regarding the composition is prepared as a tablet for treating living object as claimed in claims 15 and 24 in addition to what is claimed in claim 1 as a whole.

(m) Li is silent regarding the composition is prepared as a solution for treating living object as claimed in claims 16 and 25 in addition to what is claimed in claim 1 as a whole.

(n) Li fails to teach the composition is prepared into a predetermined form for administration that contains 1 to 300 mg/kg/dl of the active ingredients as claimed in claims 17 to 20 in addition to what is claimed in claim 1 as a whole.

Whether the claims 1-6 and 9-25 as amended of the instant invention are obvious depends on whether the above differences (a) to (n) between the instant invention and Li are obvious in view of Song, Jiang, Wang, Chen, Hsu, Takahashi, Grayer-Berkmeijer, Yoshikawa, Somava, Li et al, and/or Prasad at the time of the invention was made.

Furthermore, the applicant respectfully submits that when applying 35 USC 103, the following tenets of patent law must be adhered to:

- (a) The claimed invention must be considered as a whole;
- (b) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;
- (c) The references must be viewed without the benefit of hindsight vision afforded by the claimed invention; and
- (d) Reasonable expectation of success is the standard with which obviousness is determined.

Also, "The mere fact that a reference could be modified to produce the patented invention would not make the modification obvious unless it is suggested by the prior art." Libbey-Owens-Ford v. BOC Group, 4 USPQ 2d 1097, 1103 (DCNJ 1987).

Song, Jiang, Wang, Chen, Hsu, Takahashi, Grayer-Berkmeijer, Yoshikawa, Somava, Li et al, and/or Prasad merely teach the individual component without providing a composition including berberine, catalpol, and oleanolic acid for treating living object with non-insulin dependent diabetes mellitus. Generally speaking, most Chinese medicines contain two or more ingredients combining with each other to minimize the side effect of each ingredient. For example, berberine itself is toxicity and may cause heart disease and lower the blood pressure. The composition of berberine, catalpol, and oleanolic acid can minimize the side effect of berberine and allows the living object, especially for human being, for administration. In fact, neither Li, Song, Jiang, Wang,

Chen, Hsu, Takahashi, Grayer-Berkmeijer, Yoshikawa, Somava, Li et al, nor Prasad suggests a method of treating a living object for administration containing the above distinctive features (a) to (n) as claimed in the instant invention as well as any combination or possibility of providing a composition including berberine, catalpol, and oleanolic acid for treating living object with non-insulin dependent diabetes mellitus.

“To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the examiner to show a motivation to combine the references that create the case of obviousness. In other words, the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited art references for combination in the manner claimed... [T]he suggestion to combine requirement stands as a critical safeguard against hindsight analysis and rote application of the legal test for obviousness...” *In re Gorman*, 933 F.2d 982, 986, 18 USPQ 2d 1885, 1888 (Fed. Cir. 1991).

Accordingly, the applicant believes that neither Li, Song, Jiang, Wang, Chen, Hsu, Takahashi, Grayer-Berkmeijer, Yoshikawa, Somava, Li et al, nor Prasad, separately or in combination, suggests or makes any mention whatsoever of the difference subject features (a) to (n) as claimed in the amended claims 1-6 and 9-25 of the instant invention.

Applicant believes that for all of the foregoing reasons, all of the claims are in condition for allowance and such action is respectfully requested.

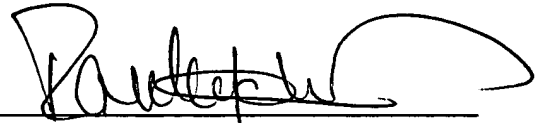
#### **The Cited but Non-Applied References**

The cited but not relied upon references have been studied and are greatly appreciated, but are deemed to be less relevant than the relied upon references.

In view of the above, it is submitted that the claims are in condition for allowance. Reconsideration and withdrawal of the objection are requested. Allowance of claims 1-6 and 9-25 at an early date is solicited.

Should the Examiner believe that anything further is needed in order to place the application in condition for allowance, he is requested to contact the undersigned at the telephone number listed below.

Respectfully submitted,

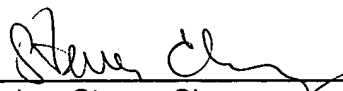


Raymond Y. Chan  
Reg. Nr.: 37,484  
108 N. Ynez Ave.  
Suite 128  
Monterey Park, CA 91754  
Tel.: 1-626-571-9812  
Fax.: 1-626-571-9813

#### CERTIFICATE OF MAILING

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Person Signing: Steven Cheung